

**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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ABBOTT GMBH & CO., KG, )  
ABBOTT BIORESEARCH CENTER, INC. )  
AND ABBOTT BIOTECHNOLOGY LTD., )  
 )  
Plaintiffs, )  
 )  
v. )  
 )  
CENTOCOR ORTHO BIOTECH, INC. AND )  
CENTOCOR BIOLOGICS, LLC., )  
 )  
Defendants. )  

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Civil Action No. 4:09-cv-11340-FDS

**PLAINTIFFS' POST HEARING MARKMAN BRIEF**

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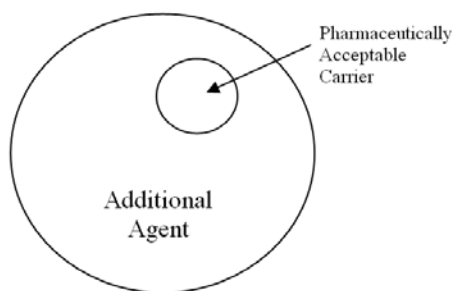
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# I. ABBOTT’S PROPOSED CONSTRUCTIONS SHOULD BE ADOPTED

## A. “Additional Agent”

ABBOTT’S PROPOSED CONSTRUCTION	CENTOCOR’S PROPOSED CONSTRUCTION
Plain meaning	“an agent other than a pharmaceutically acceptable carrier which imparts a beneficial attribute to the therapeutic composition”

The term “additional agent,” as used in the patent, describes just what it states: something additional in addition to the antibody, or antigen-binding portion thereof, that is in the claimed composition.



Centocor concedes that the description in the patent specification of “additional agent” is broad enough to encompass “pharmaceutically acceptable carriers.” (*See* Centocor’s Opening Br. at 15). Centocor nevertheless erroneously asserts that the term should be narrowed to exclude “pharmaceutically acceptable carriers” because of a convoluted argument in which it claims Abbott “surrendered ‘pharmaceutically acceptable carriers’ from the scope of the term ‘additional agents’ during prosecution of the ‘485 patent.” *Id.* Centocor’s argument hinges on the PTO’s determination that, while claim 64 of the ‘128 patent interfered with certain claims of Centocor’s ‘994 application, application claim 142 of the ‘485 patent (which became issued ‘485 claim 1) did not. Centocor asserts that the only difference between ‘128 claim 64 (which was found to interfere) and ‘485 application claim 142 (which was found not to interfere) was the inclusion of “pharmaceutically acceptable carrier” in the former and “additional agent” in the

latter. Centocor argues that Abbott added “additional agent” to ‘485 application claim 142 in order to make that claim “patentably distinct” and “different” from ‘128 patent claim 64. *Id.* at 15, 17-19; *see also* slides 18-19 from Centocor’s Markman Presentation (Ex. 9).<sup>1</sup>

Centocor’s argument is wrong for each of the following reasons, and for the reasons set forth in the Declaration of Bruce H. Stoner Jr. dated Nov. 19, 2010 (“Stoner Decl.”), which accompanies this brief:

*First*, Centocor’s assertion that Abbott amended ‘485 application claim 142 to make it “patentably distinct” from ‘128 patent claim 64, i.e., so the claims did not interfere with each other, simply doesn’t make sense. An interference is a proceeding to determine which of two different entities has the right to the same inventive subject matter that both have claimed. Patent claims contained in related applications having identical inventors and that are owned by the same entity *cannot interfere with one another as a matter of law*. *See* 35 U.S.C. 102(g)(1) (“A person shall be entitled to a patent unless . . . during the course of an interference . . . another inventor involved therein establishes . . . that before such person’s invention thereof the invention was made by such other inventor . . . [or] by another inventor . . . .”); Stoner Decl. ¶ 10. If the same inventive entity has claims in different patents that are of the same scope, the vehicle for addressing that situation is the doctrine of double patenting. *See, e.g., Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001); Stoner Decl. ¶ 11. As such, there is no relevance to whether the claims of Abbott’s two patents are patentably distinct from one

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<sup>1</sup> References to “Ex.” refer to exhibits attached to the Decl. of Robert J. Gunther, Jr., filed concurrently herewith.

another.<sup>2</sup> Consistent with interference law, neither the PTO nor Abbott compared, or would have had any reason to compare, ‘128 claim 64 and ‘485 application claim 142. *See* Stoner Decl. ¶ 10. Instead, in determining whether an interference existed, the PTO compared the claims of the ‘128 patent with the claims in the Centocor ‘994 application. The PTO later separately compared the claims of the then-pending ‘485 application to determine whether those claims interfered with the Centocor patent application claims. The prosecution history shows that the exchange between Abbott and the PTO focused solely on amendments to the ‘485 application claims that would cause them not to interfere with the Centocor patent application claims. In short, Centocor’s assertion that Abbott amended ‘485 application claim 142 to make it patentably distinct from ‘128 claim 1 is factually and legally incorrect.

*Second*, even assuming, *arguendo*, that Abbott had amended the claims of the ‘485 patent to make them patentably distinct from the claims of the ‘128 patent, this does not mean that the terms “pharmaceutically acceptable carrier” and “additional agent” are mutually exclusive terms. *See* Stoner Decl. ¶ 20. It is well-settled that claims which overlap (as shown by the diagram on page 1) can be patentably distinct from one another such that they do not interfere. For example, in certain instances, a claim to a species or a sub-genus can be patentably distinct from another

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<sup>2</sup> In this case, the Examiner rejected claims of the ‘485 application on grounds of double patenting in view of the ‘128 patent. *See* Stoner Decl. ¶ 12. *See* ‘485 patent prosecution history, Office Action of June 4, 2007 (Ex. 3) at 12. Abbott was not required to make any claim amendments or arguments with respect to the respective scope of the claims in the two patents in order to overcome this rejection. *See* Stoner Decl. ¶ 14. Instead, it filed what is known as a “terminal disclaimer,” pursuant to which Abbott agreed that the later applied for claims of the ‘485 patent would expire at the same time that the earlier filed ‘128 patent expires. *See* Stoner Decl. ¶ 14; ‘485 patent prosecution history, Terminal Disclaimer of April 22, 2008 (Ex. 4). A terminal disclaimer only acts to shorten the term of the later-filed overlapping claims. *See* Stoner Decl. ¶ 14. It has no impact on the scope of the claims of the later-filed patent, and it is not an admission that a later-filed patent is obvious. *See, e.g., Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007) (“A terminal disclaimer simply is not an admission that a later-filed invention is obvious”); *In re Longi*, 759 F.2d 887, 894 (Fed. Cir. 1985) (“A patent may still issue if an applicant faced with [a double patenting] rejection were to file a terminal disclaimer under 35 U.S.C. § 253, disclaiming ‘any terminal part of the term ... of the patent,’ thereby guaranteeing that the second patent would expire at the same time as the first patent.”); *Regents of the Univ. of Minn. v. AGA Med. Corp.*, 660 F. Supp. 2d 1037, 1040 (D. Minn. 2009) (“A terminal disclaimer is, in essence, a concession by the patentee that two patents that resulted from the same application should be treated as a single patent, effective for a single patent term. Put differently, the claims of the continuation patent are treated as if they appeared in the first patent.”).

claim to a genus that includes that species or sub-genus. *See Eli Lilly & Co. v. Board of Regents of the Univ. of Wash.*, 334 F.3d 1264, 1268-70 (Fed. Cir. 2003) (in an appeal relating to whether an interference existed between a genus claim and another claim to a species of that genus, the Federal Circuit stated that “it is possible that both the genus and the species are separate patentable inventions”); *See Stoner Decl.* ¶ 19.<sup>3</sup> Another way of stating this principle is that a claim which is a subset of a second claim can nevertheless be patentably distinct from the broader second claim. *See Stoner Decl.* ¶ 19. For example, if A and B both have claims to a jet airplane, those claims are not patentably distinct and therefore interfere with one another. In contrast, if A also had a claim to an airplane, that claim would not necessarily interfere with B’s claim to a jet airplane. One claim is a subset of the other, but they can be patentably distinct.

This is the situation here, since, as Centocor concedes based on the specification, “pharmaceutically acceptable carrier” (the term used in ‘128 claim 64) is a subset of “additional agent” (the term used in ‘485 application claim 1). *See Centocor’s Opening Br.* at 15. In short, even if Abbott had amended ‘485 application claim 142 to make it patentable distinct from ‘128 claim 64, that would not support Centocor’s conclusory assertion that the two claim terms must be mutually exclusive.<sup>4</sup> *See Stoner Decl.* ¶ 20. The most that can be said of the amendment is that it indicates that the two phrases are not synonymous.

*Third*, none of the cases cited by Centocor remotely justify the flawed chain of inferences

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<sup>3</sup> In determining whether two claims interfere, the Patent Office does not require that the two claims cover mutually exclusive subject matter. Instead, it applies what is called the two-way test. *See Stoner Decl.* ¶ 16. Pursuant to that test, claim A is the same patentable invention as claim B, and therefore the claims interfere, when claim A is the same as or is obvious in view of claim B *and* when Claim B is the same as or obvious in view of claim A. *Eli Lilly*, 334 F.3d at 1269. *See Stoner Decl.* ¶ 16-19.

<sup>4</sup> There are other differences between ‘128 claim 64 and ‘485 application claim 142 beyond “pharmaceutically acceptable carrier” and “additional agent.” For example, ‘485 claim 142 recites an antibody that is “capable of binding to an epitope of the p40 subunit of IL-12” whereas ‘128 claim 64 requires (by reference to claim 1) an antibody that “binds to human IL-12.” Also, ‘128 claim 64 requires (by reference to claim 1) that the recited antibody must dissociate from human IL-12 with a  $K_D$  of  $1 \times 10^{-10}$  M or less and a  $k_{off}$  rate constant of  $1 \times 10^{-3} \text{ s}^{-1}$  or less, while ‘485 claim 142 contains no such limitation. These additional differences further undermine Centocor’s argument, because it is impossible to tell whether these differences (either alone or in combination with the differences between “pharmaceutically acceptable carrier” and “additional agent”) had an impact on the PTO’s separate determinations as to whether the claims of the ‘128 and ‘485 patents interfered with the claims of the Centocor ‘9984 application.

on which Centocor is forced to rely. In fact, Centocor does not cite any cases that address prosecution disclaimer in the context of an interference. *See Rhodia Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (finding disclaimer of particular structure, where prosecution history revealed that patentee had explicitly distinguished claimed invention from prior art to overcome unpatentability); *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323-24 (Fed. Cir. 2003) (finding disclaimer of particular function, where, during prosecution, patentee had attempted to overcome prior art by proffering narrower meaning of claimed function); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1326-27 (Fed. Cir. 2003) (finding no disavowal of claim terms despite alleged infringer's attempt to infer intentional narrowing of claim based upon alleged representations made by patentee during prosecution); *Binckley v. United States*, 83 Ct. Cl. 444, at \*14-16 (Ct. Cl. 1936) (finding that patentee relinquished certain elements of his invention because patentee had "voluntarily canceled certain claims and amended a substituted one to meet repeated rejections of the same by the Patent Office upon references to the prior art"). Abbott is not aware of any cases discussing prosecution disclaimer in an interference context that have facts even remotely resembling the situation here, namely where a disclaimer is inferred based on a determination of the scope of a claim in a different patent, despite the fact that neither the PTO nor the applicant said anything about the other patent claim in connection with the amendment to the claim in issue.

*Finally*, in those cases in which a prosecution disclaimer was found, the applicant ***clearly and unmistakably*** surrendered claimed subject matter in the course of obtaining issuance of the claims at issue. *See, e.g., Omega Eng'g*, 334 F.3d at 1323-24. Here, in contrast, in the remarks accompanying its amendments to the '485 patent claims, Abbott at no point mentioned the claims of its own '128 patent, and made no comparison at all of the term "pharmaceutically

acceptable carrier” in claim 64 of its ‘128 patent with the term “additional agent” as used in the claims of its ‘485 patent, and certainly did not add the term “additional agent” to make the claims patentably distinct from the claims of the ‘128 patent. (*See* Supplemental Amendment of October 10, 2008 (Ex. 5).<sup>5</sup> In the face of this silence from Abbott, Centocor’s counsel was forced to concede during the hearing that its argument was based on *inferring* what Abbott meant when it amended claim 1 of the ‘485 patent. *See* Transcript of Markman Hearing (Ex. 7) at 118:3-6. But the doctrine of prosecution disclaimer does not operate by inference. To the contrary, there must be a ***clear and unmistakable*** disclaimer of subject matter for prosecution disclaimer to occur. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1321 (Fed. Cir. 2008); *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1306 (Fed. Cir. 2003). *See also Middleton, Inc. v. Minnesota Mining & Mfg. Co.*, 311 F.3d 1384, 1388 (Fed. Cir. 2002); *Sky Technologies, LLC v. Ariba, Inc.*, 491 F. Supp. 2d 154, 158 (D. Mass. 2007); Abbott Reply Br. at 7-9.

For all of these reasons, as well as those set forth in Abbott’s pre-hearing briefs, Centocor’s attempt to infer a prosecution disclaimer in order to narrow the scope of the “additional agent” term used in the ‘485 patent claims should be rejected and the Court should adopt the plain meaning of this term as Abbott has proposed.

#### **B. “Neutralizing Antibody”**

<b>ABBOTT’S PROPOSED CONSTRUCTION</b>	<b>CENTOCOR’S PROPOSED CONSTRUCTION</b>
“an antibody whose binding to an antigen results in inhibition of a biological activity”	“an antibody whose binding to human IL-12 results in inhibition of the biological activity of human IL-12”

At the Markman hearing there was some discussion about whether or not the parties might be in agreement regarding the construction of the term “neutralizing antibody,” at least in

<sup>5</sup> There is no statement by the PTO or in Abbott’s Supplemental Amendment (Ex. 5) that directly addresses the term “additional agent,” the term “pharmaceutically acceptable carrier,” or the relationship between the two terms. Similarly, there is no discussion of the amendment or any of these claim terms in any Interview Summary or other part of the prosecution history of the ‘485 patent.

relation to its usage in the claims of Abbott's '128 patent. *See* Ex. 7 at 78-79. Without conceding the correctness of Centocor's position, Abbott is willing to agree for purposes of this case that, in the context of the claims of the '128 patent only, a "neutralizing antibody" is an antibody that neutralizes IL-12.<sup>6</sup> The term "neutralizing antibody" by itself is not limited to neutralizing IL-12, but within the context of the claims, where that term is used in claims that require that the antibody bind to IL-12, the antibody neutralizes IL-12. As noted in Abbott's Opening Br. at 15-16, there are also claims of the '485 patent, *e.g.*, claims 15 and 25, that recite a neutralizing antibody that binds to the P40 subunit of an interleukin. The differing language of these claims makes clear that it would be inappropriate to limit these claims to an antibody that neutralizes IL-12. *See also* Abbott's Markman Presentation, slides 11-12 (Ex. 8).

**C. Assay Related Claim Terms.**

CLAIM TERM	ABBOTT'S PROPOSED CONSTRUCTION	CENTOCOR'S PROPOSED CONSTRUCTION
"inhibits phytohemagglutinin blast proliferation in an in vitro PHA assay"	"inhibits the proliferation of stimulated human PHA blasts"	"inhibits the proliferation of human PHA blasts stimulated by IL-12"
"inhibits human IFN $\gamma$ production"	Plain meaning	"inhibits the production of human interferon- $\gamma$ by human PHA blasts stimulated by IL-12"
"inhibits IL-12 binding to its receptor in an IL-12 receptor binding assay (RBA)"	Plain meaning	"inhibits IL-12 binding to IL-12 receptors on human PHA blasts"

Centocor does not dispute the meaning of the words of the claims, but seeks to import additional limitations from the specification that are not in the claims as written. In particular, Centocor seeks to add: (a) a limitation that a PHA assay must be conducted using PHA blasts stimulated by IL-12; (b) a limitation that the IFN $\gamma$  whose production is inhibited by the recited

<sup>6</sup> As noted in our briefing and during the hearing, other language in the claims of the '128 patent specifies that the recited antibody is one that binds to human IL-12. *See* Abbott Reply Br. at 3-4; Ex. 7 at 61.

antibodies must be IFN $\gamma$  produced by PHA blast cells stimulated by IL-12; and (c) the limitation that the recited antibodies must inhibit IL-12 binding to IL-12 receptors on human PHA blast cells. However, the law is clear that even when the specification describes only a single embodiment, a court will not limit broader claim language to that single embodiment “unless the patentee has demonstrated a clear intention to limit the claim scope ‘using words or expression of manifest exclusion or restriction.’” *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002))). The common specification of Abbott’s ‘128 and ‘485 patents contains no words or expression of manifest exclusion or restriction in relation to the disputed assay terms. On the contrary, the specification merely provides non-limiting examples of assays that can be used. *See* ‘128 Patent, Col. 82, ll. 60-62. Furthermore, the specification expressly states that other assays known in the art can be used. *See* ‘128 Patent, Col. 27, ll. 53-65.

During the Markman hearing, Centocor argued that, because Abbott’s claims do not recite precise details of the particular assays described in Abbott’s Example 3, Centocor is left “wondering exactly what [Abbott is] going to come up with in [its] expert report to show infringement.” *See* Ex. 7 at 93:10-12. In essence Centocor argues that their constructions should be adopted in order to limit the type of evidence that Abbott can rely on to prove infringement. Centocor’s argument mirrors the unsuccessful argument made by ImClone in *Massachusetts Institute of Technology v. ImClone Systems, Inc.*, 498 F. Supp. 2d 435 (D. Mass. 2007). In that case, the claims recited the term “tissue specific” in relation to “an enhancer.” The defendant, ImClone, argued that the claim should be limited to the specific “tissue” described in the patent specification because without this limitation plaintiffs could “cherry pick” the test used to

demonstrate infringement. *Id.* at 438-39. The court dismissed ImClone's argument, stating "[a]t bottom, whatever their weight, ImClone's arguments go to the issues of validity and infringement, and have no real bearing on claim construction. They are, in other words, arguments to be made to the jury and not to the court." *Id.* at 439. So too here, the question of whether or not infringement could be demonstrated using tests not specifically disclosed in Abbott's Patents should play no role in the claim construction process.

## II. CONCLUSION

For the reasons set forth herein, in addition to those articulated in Abbott's opening brief, reply brief, and oral Markman argument, Abbott respectfully requests the Court construe the disputed claim terms as follows:

CLAIM TERM:	ABBOTT'S PROPOSED CONSTRUCTION:
"neutralizing antibody"	"an antibody whose binding to an antigen results in inhibition of a biological activity"
"inhibits phytohemagglutinin blast proliferation in an in vitro PHA assay" or "inhibits phytohemagglutinin blast proliferation in an in vitro phytohemagglutinin blast proliferation assay (PHA) assay"	"inhibits the proliferation of stimulated human PHA blasts"
"inhibits human IFN $\gamma$ production"	Plain meaning
"inhibits IL-12 binding to its receptor in an IL-12 receptor binding assay (RBA)"	Plain meaning
"additional agent"	Plain meaning

CLAIM TERM	AGREED UPON CONSTRUCTION
"K <sub>d</sub> "	"the dissociation constant of a particular antibody-antigen interaction"
"k <sub>off</sub> "	"the off rate constant for dissociation of an antibody from the antibody/antigen complex"
"surface plasmon resonance"	"an optical phenomenon that allows for the analysis of real-time biospecific interactions by detection of alterations in protein concentrations within a biosensor matrix"
"recombinant antibody"	"antibody that is prepared, expressed, created or isolated by recombinant means"

“pharmaceutically acceptable carrier”	“any and all solvents, dispersion media, coatings, antibacterial and antifungal agents, isotonic and absorption delaying agents, and the like that are physiologically compatible, including one or more of water, saline, sugars, alcohols, polyalcohols, wetting or emulsifying agents, preservatives or buffers.”
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DATE: November 19, 2010

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**CERTIFICATE OF SERVICE**

I certify that, on November 19, 2010, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

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